UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

In re Novartis and Par Antitrust Litigation	1:18-cv-04361-AKH
This Document Relates To: All Actions	FILED UNDER SEAL

PLAINTIFFS' MEMORANDUM IS SUPPORT OF THEIR MOTION TO EXCLUDE THE OPINIONS OF DEFENDANTS' PATENT LITIGATION EXPERT MR. PHILLIP JOHNSON ON WHAT "REASONABLE COMPANIES" WOULD HAVE BELIEVED ABOUT THE STRENGTH OF NOVARTIS'S PATENTS

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Plaintiffs request that this Court exclude the expert opinions of Mr. Philip Johnson relating to what "reasonable companies" would have believed about Novartis's likelihood of success in asserting the '197 and '728 Patents against Par's generic Exforge. These opinions are unreliable, do not fit the facts of the case, and/or are contrary to law.

I. INTRODUCTION

In reverse-payment cases like this one, plaintiffs prove violations of the antitrust laws under the antitrust rule of reason. *See FTC v. Actavis*, *Inc.*, 570 U.S. 136, 159 (2013). In that analysis, the focus is on whether the brand pharmaceutical manufacturer made a large payment to a generic manufacturer to avoid the risk of generic competition. *Id*. at 157-58. The Supreme Court explained that in reverse-payment cases, "it is normally not necessary to litigate patent validity to answer the antitrust question." *Id*. at 157.

Nevertheless, both Plaintiffs and Defendants have identified experts who opine on the validity and infringement of patents that Novartis claimed covered Exforge, its branded valsartan and amlodipine product approved for the treatment of hypertension. Opinions about the *perceived* strength or weakness of Novartis's patents at the time of the settlement may be relevant to some extent as circumstantial evidence of the reasons for a reverse payment. *Id*. at 158 (identifying the reasons for reverse payment as "the relevant antitrust question").[1] But Plaintiffs offer their patent experts principally to show that any violation that they prove under the rule of reason caused them antitrust injury.

[1] Where, as here, a party has asserted privilege to block discovery of its subjective beliefs regarding patent strength, however, it cannot offer expert opinion testimony as a surrogate for what its actual beliefs were. *In re Namenda Direct Purchaser Antitrust Litig.*, 15-cv-7488 (CM), ECF No. 859 at 15 ("[I]f [the defendant Forest's expert] testifies about his views on the strength of the patent, the litigation and the settlement, the jury will be specifically advised that it cannot draw the conclusion that Forest actually held the same views as [its expert].").

For example, one of Plaintiffs' causation theories is that, absent Defendants' reverse-payment violation, it would have been in Defendants' economic interests to agree to an earlier entry date for generic Exforge and enter a license agreement (just as they did in the real world, only without a reverse payment).[2] Plaintiffs' expert economists model this earlier entry date using standard economic theory concerning the settlement of litigation, estimates of how the merits of the patent litigation would have been perceived by the parties at the time of the challenged agreement, and the parties' financial forecasts. Such models have been universally accepted by the courts to show the but-for entry date in reverse-payment cases.[3]

As an input for their economists' models, Plaintiffs proffer the opinion of patent attorney Mr. Belvis to opine on how a reasonable patent litigator would have assessed Par's chances of success in the patent litigation at the time that Novartis and Par entered the challenged license agreement and would have advised a reasonable company in the position of Novartis and Par. To rebut these opinions, Defendants offer Mr. Johnson, a patent lawyer who claims that Novartis was more than 50% likely to win in patent litigation against Par.

While ordinarily this might be a battle of the experts, Mr. Johnson's "reasonable company" opinions on patent strength must be excluded under *Daubert* and Rule 702. First, Mr. Johnson's

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[2] *FTC v. Actavis*, 570 U.S. at 158 (2013) ("[T]he fact that a large, unjustified reverse payment risks antitrust liability does not prevent litigating parties from settling their lawsuit. They may, as in other industries, settle in other ways, for example, by allowing the generic manufacturer to enter the patentee's market prior to the patent's expiration, without the patentee paying the challenger to stay out prior to that point.").

[3] *See, e.g.*, *United Food & Comm'l Workers Local 1776 & Participating Employers Health &Welfare Fund v. Teikoku Pharma USA*, 296 F. Supp. 3d 1142, 1162-63 (N.D. Cal. 2017) (denying motion for summary judgment on causation based expert opinions of plaintiffs' economists on alternative entry dates that would have been economically rational absent reverse payment); *In re Solodyn (Minocycline Hydrochloride) Antitrust Litig.*, 2018 WL 563144, at *23 (D. Mass. 2018) (same); *In re Opana ER Antitrust Litig.*, 2021 WL 2291067 (N.D. Ill. 2021) (same).

opinions are unreliable because he relies on law and facts that were not available at the time the challenged license agreement between Novartis and Par ("the NPLA") was executed, and therefore his opinions do not fit the facts of this case and are unreliable.

Second, Defendants' documents and conduct show that the conclusion that Defendants reached about the patent merits was precisely the opposite of the opinion that Mr. Johnson seeks to offer. Internal Novartis documents show that it agreed with Par's assessments that Par had "designed around" Novartis's patents and with a financial analyst's conclusion there was a "high probability that Exforge will face generic competitors in 2012 due to likely invalidation of" the '728 Patent. In addition, the negotiation history between Novartis and Par show that they both anticipated that Novartis would surrender the majority of the patent life on its patents to Par. Such a conclusion would not make rational economic sense if Novartis and Par believed that Novartis was likely to win the patent litigation. A patent win would preserve the entire patent term (until July 8, 2019, for the '728 Patent) for Novartis. Defendants' conduct can only be squared with the conclusion that the patents were unlikely to afford Novartis any exclusivity.[4]

II. FACTUAL BACKGROUND

A. Par's Certification that the '197 and '728 Patents are Invalid or Not Infringed

Novartis listed three patents in the FDA Orange Book for Exforge—the '197 Patent, the '728 Patent, and U.S. Patent No. 5,399,578 ("the '578 Patent"). Ex. 11,[5] NPC_00028451, at -451-59. In October 2007, Par submitted abbreviated new drug application ("ANDA") No. 90-011 for generic Exforge, (Ex. 12, PAR-000065547, at -549) which it subsequently amended to include

[4] Mr. Johnson's patent strength opinions should also be excluded as unreliable for the reasons set forth in Plaintiffs' contemporaneously filed *Daubert* motions seeking to exclude Defendants' technical experts' opinions on the validity and infringement of the '197 and '728 Patents.

[5] References to exhibits herein are to the exhibits attached to the Declaration of Dan Litvin, submitted contemporaneously herewith.

three additional dosage strengths (Ex. 13, PAR-000111236, at -238; Ex. 15, PAR-000096348, at -350; Ex. 14, PAR-000087208, at -210). Par's ANDA included a Paragraph III certification for the '578 Patent, committing Par not to market generic Exforge before that patent expired on September 21, 2012. *Id*. at -577. As to the '197 and '728 Patents, Par "certifie[d] that in its opinion and to the best of its knowledge" the '197 and '728 Patents were "invalid, unenforceable, or will not be infringed by the manufacture, use, or sale" of Par's generic Exforge products. *Id*. at -578-79. Par also certified that Par "will market" generic Exforge "upon approval of [its] abbreviated new drug application, but not prior to . . . September 21 2012. . . ." *Id*. at -580.

On December 7, 2007, Par sent Novartis a 56-page notice letter disclosing its Paragraph IV certification and providing a "Detailed Statement of the Factual and Legal Bases" for its "Opinion That [the '197 and '728 Patents] Are Invalid and/or Will Not Be Infringed." Ex. 20, NPC_01190838, at -838, -840. With respect to the '197 Patent, Par asserted that its "proposed formulation will not infringe any claim of the '197 patent because it will contain less than 35% valsartan by weight." *Id*. at -841. With respect to the '728 Patent, Par asserted that its "proposed formulation will not infringe the claims directed to a method of treating 'hypertension associated with-diabetes' because Par's proposed formulation will not be indicated for this use." *Id*. at -842. Par also asserted that "[e]ach and [e]very [c]laim of the '728 Patent is [i]nvalid." *Id*. at -880.

B. Novartis's Conclusion That the '197 and '728 Patents Were Too Weak to Assert Against Generic Exforge.

Internally, Novartis recognized that the '197 and '728 Patents were extremely weak and incapable of excluding generic competition. By February 2008, shortly after receiving Par's Paragraph IV certification notice letter, Novartis concluded that, due to patent problems, "Exforge profitability needs to be maximized in the near term." Ex. 21, NPC_02028740, at -806. With

respect to the '197 Patent, Novartis concluded, consistent with Par's Paragraph IV certification and notice letter, that "Generics have designed around this" patent. *Id*.[6]

Even before receiving Par's Paragraph IV notice letter, Novartis concluded that the '728 Patent was seriously flawed. On April 26, 2007, Morgan Stanley analyst Andrew Baum published an article titled "US Supreme Court ruling to Raise Pharma Patent Risk" that explained the likely impact of the Supreme Court's decision in *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398 (2007) ("*KSR*"), on patents directed to combination drugs like Exforge. Ex. 48, NPC_01881056. Mr. Baum's article specifically called out the '728 Patent as being at significant risk: "We place a high probability that Exforge will face generic competitors in 2012 due to likely invalidation of their pivotal . . . 6,395,728 patent[]." *Id*. at -059. On April 30, 2007, Novartis's Senior Vice President & Chief Marketing Officer[7] Nancy Lurker emailed Novartis's Chief Executive Officer Alex Gorsky[8], stating: "I agree with the Morgan Stanley assessment, we need to think about . . . no Exforge post [September 21, 2012]." Ex. 25, NPC_01520380, at -380.

C. Par Plans to Launch Generic Exforge When the '578 Patent Exclusivities Expired in 2012; Novartis Expects Generic Entry in 2012

Consistent with its certification to FDA that it "will market" its generic Exforge product upon final approval from FDA, *supra*, Par prepared for a launch in September 2012. In slides prepared for a Board of Directors Meeting in 2008, Par President Paul Campanelli informed the Board that Par's "Plan" was "Launching on '578 patent expiry (9/2012)." Ex. 26, PAR-000311396,

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[6] To "design around" a patent means "to design a product or process that does not infringe." *Hilton Davis Chem. Co. v. Warner-Jenkinson Co.*, 62 F.3d 1512, 1520 (Fed. Cir. 1995), *rev'd on other grounds*, *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17 (1997). The Novartis presentation did not refer to the '197 Patent by its patent number, but it identified a patent with an expiration date of June 18, 2017 and a pediatric exclusivity date of December 18, 2017, and the '197 Patent is the only Exforge patent with those dates. Ex. 49, 2008 Orange Book Excerpt, at 4.

[7] Ex. 23, NPC_01863340 at -340.

[8] Ex. 24, NPC_01868814 at -814-815.

at -409. An "Executive Committee Meeting" presentation in January 2009 reflected that Par remained committed to a September 2012 launch. Ex. 27, PAR-000311873, at -879. And Par's forecasts show that from 2008 to 2011, Par planned to launch generic Exforge on September 21, 2012. Ex. 28, PAR-000149301, at -301_0024 (February 28, 2008 forecast showing "9/21/2012" is the "Estimated Launch Date" for "Amlodipine Besylate/Vasartan Tablets"); Ex. 29, PAR-000364194 (April 19, 2011 forecast shows generic Exforge launch "Sep-12").[9] On March 22, 2011, in response to its partner Synthon's email that it was "excited about Par being [our] partner to successfully launch [generic Exforge] in September 2012," Mr. Campanelli responded "We look forward to launching." Ex. 33, PAR-000354813, at -813.

Novartis also consistently "anticipated Gx [generic] entry" following expiration of the '578 Patent on "Sep 21, 2012," notwithstanding the existence of the '197 and '728 Patents. Ex. 34, NPC_01029179, at -295. Novartis recognized that generic drug companies like Par were "aggressively challeng[ing] patents" and "launch[ing] at risk" Ex. 35, NPC_01819573, at -583. Accordingly, Novartis forecast that "[g]enerics are expected to enter on September 21, 2012 at expiration of the valsartan compound patent — this impacts . . . Exforge. . . ." Ex. 36, NPC_00045104, at -106; *see also* Ex. 37, NPC_00205782, at -785 ("Exforge expected to lose market exclusivity in 2012"); Ex. 38, NPC_00068305, at -313 (planning for loss of exclusivity on Exforge in September 2012); Ex. 39, NPC_00786922, at -925 ("Exforge & Exforge HCT are also expected to face generic competition in September 2012").[10]

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[9] *See also* Ex. 30, PAR-000347696, at -727 (March 5, 2009 email attaching forecast with "Target Launch Date" of "9/21/12"); Ex. 31, PAR-000321264, at -305 (November 23, 2009 forecast showing "9/21/12" target launch date); Ex. 32, PAR-000185118 (July 7, 2010 forecast showing "September 2012" launch date).

[10] *See also* Ex. 40, NPC_02023625, at -628 ("Expected Gx entry" for Exforge on "Sept. 21 2012"); Ex. 41, NPC_01363109 at -149 ("Payors assume Exforge LOE Sept 2012"); Ex. 42,

D. Anticipated Licensed Entry Date in Mid-2013.

In early settlement discussions, Novartis and Par both contemplated a negotiated resolution to their patent dispute in which Novartis licensed Par to launch generic Exforge in the third quarter of 2013. By early 2010, Novartis planning documents show that, although "Expected Gx Entry" was "Sept. 21, 2012" for generic Exforge, "IP negotiations [were] underway." Ex. 40, NPC_02023625, at -628. By late-June 2010, Par had "signaled a willingness to speak about a settlement to avoid a launch at risk" and for "the Strat Plan we [Novartis] have assumed a settlement provision [with Par] for Exforge mono which takes it to ***Sep 2013***." Ex. 44, NPC_00552058, at -058 (emphasis added). On June 13, 2011, Par patent attorney Larry Brown sent Par President Paul Campanelli a first draft of a license agreement. Ex. 45, PAR-000458637. In this draft, Par proposed a ***royalty-free*** license under the '197 and '728 Patents with a generic entry date of ***July 1, 2013***. *Id.* at -639. Par's first draft did not include any provision limiting Novartis's ability to launch an authorized generic ("AG" or "AGx") in competition with Par. *Id.*

III. MR. JOHNSON'S CHALLENGED OPINIONS

Mr. Johnson opines that "reasonable companies" in Novartis's and Par's positions would have anticipated that Novartis would "likely" have won a patent infringement litigation involving the '197 and '728 Patents. *See, e.g.*, Ex. 1, Johnson Rpt., ¶¶ 145, 385; *see also id.* ¶¶ 330, 333, 469. At his deposition, he testified that by "likely," he meant "greater than 50%." Ex. 2, Johnson Dep., at 106:7-12; 109:5-13; 112:14-17.

IV. LEGAL STANDARD

Under Federal Rule of Evidence 702, expert testimony must be "based on sufficient facts or data"; the expert's opinion must be "the product of reliable principles and methods"; and the

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NPC_00530452, at -453 ("Exforge LOE: September 2012"); Ex. 43, NPC_01790406, at -408, -413 ("Diovan and Exforge LOE: September 2012).

expert must have "reliably applied the principles and methods to the facts of the case." *Electra v. 59 Murray Enters.*, 987 F.3d 233, 254 (2d Cir. 2021). "In determining admissibility under *Daubert*, trial judges are charged with a gate-keeping function pursuant to Rule 702 whereby they must determine (1) whether the theory or methodology underlying the testimony is reliable and (2) whether the expert's theory or methodology is relevant in that it 'fits' the facts of the case." *Astra Aktiebolag v. Andrx Pharms., Inc.*, 222 F. Supp. 2d 423, 487 (S.D.N.Y. 2002). To be reliable, "an expert's testimony must fit the substantive law and the facts of the case." *Louis Vuitton Malletier v. Dooney & Bourke, Inc.*, 525 F. Supp. 2d 558, 679 (S.D.N.Y. 2007).

V. ARGUMENT

The Court should exclude Mr. Johnson's opinions as unreliable and contrary to law because: (1) Mr. Johnson relies upon law and facts that did not exist when the NPLA was executed; (2) his opinions cannot be reconciled with direct and circumstantial evidence of Par's and Novartis's actual beliefs; and (3) Mr. Johnson's patent strength opinions cannot be reconciled with the facts for the reasons set forth in Plaintiffs' contemporaneously filed *Daubert* motions seeking to exclude Defendants' experts' opinions on validity and infringement.

A. Mr. Johnson's Patent Strength Opinions Are Unreliable Because They Are Based on Law and Facts that Did Not Exist as of December 2, 2011

Reverse payments must be assessed at the time that the agreement is executed. *In re Tamoxifen Citrate Antitrust Litig.*, 466 F3d 187, 204 (2d Cir. 2006) (explaining that when "assessing the behavior of the defendants" in a reverse-payment antitrust case, the assessment should be conducted "at the relevant time: when they were entering into the Settlement Agreement"), *abrogated on other grounds, FTC. v. Actavis, Inc.*, 570 U.S. 136 (2013); *see also Impax Labs., Inc. v. FTC*, 994 F.3d 484, 496 (5th Cir. 2021) ("[I]t is a basic antitrust principle that the impact of an agreement on competition is assessed as of 'the time it was adopted.' That

approach also makes sense in reverse payment cases. So the focus is on the following facts as they existed when the parties adopted the settlement.") (citing *Polk Bros. v. Forest City Enters.*, 776 F.2d 185, 189 (7th Cir. 1985)); *Valley Drug Co. v. Geneva Pharms.*, 344 F.3d 1294, 1306 (11th Cir. 2003), *cert. denied*, 543 U.S. 939 (2004) ("[T]he reasonableness of agreements under the antitrust laws are to be judged at the time the agreements are entered into.").

Accordingly, Judge McMahon recently excluded expert testimony in a reverse-payment case in which a patent attorney evaluating the patent merits sought to consider facts that arose after the date of the reverse payment at issue. As she explained:

> The only things on which expert testimony about the relative merits of each party's case can be based are those that [the brand company] and [the generic company] were able to consider when evaluating whether to settle the lawsuit. Ergo, [the expert] cannot factor into her assessment things that [the brand company] and [the generic company] did not know about in 2010 [i.e., the time of the settlement] and could not possibly have known in 2010. . . . Those items did not come to light until discovery in this litigation, so a reasonable patent attorney advising a client in 2010 could not possibly have factored them into his or her equation.

In re Namenda Indirect Purchaser Antitrust Litig., 1:15-cv-6549 (CM) (RWL), 2021 U.S. Dist. LEXIS 110081 *68-69 (S.D.N.Y. June 11, 2021).

Here, Mr. Johnson's opinions are unreliable and do not fit because they rely on facts and law that did not exist as of December 2, 2011, when Novartis and Par executed the NPLA. First, in contrast to Plaintiffs' expert Mr. Belvis who cited historical reviews of the chances of success in patent cases that had been published at the time the NPLA and identified statistics that could have been considered by the parties (*see., e.g.*, Ex. 71, Belvis Rpt., ¶¶ 606-16), Mr. Johnson relies upon studies that did not exist at that time. Ex. 1, Johnson Rpt. ¶¶ 83 n.130, 91 n. 153, 587 n.1019; *see also id*. ¶¶ 81 n.119-20. Similarly, he relied on various post-NPLA legal and scientific studies to support his infringement and validity opinions. *See e.g.*, *id*. ¶¶ 472 n.839, ¶ 496 n.886, ¶ 580 n.1013, ¶ 587 n.1019.

Second, Mr. Johnson relies repeatedly on case law that did not exist in December 2011 and that therefore could not have been considered by Novartis or Par at the time they executed the NPLA. *See, e.g., id.* ¶¶ 74 n.104, 74 n.107, 198 n. 370, 270 n.505, 333 n.616, 334 n.617, 335 n. 618, 367 n.672, 373 n.677-78, 567 n.996. The starkest example is his reliance on the Federal Circuit's opinion in *Sunovion Pharms., Inc. v. Teva Pharms. USA, Inc.*, 731 F.3d 1271, 1278 (Fed. Cir. 2013), as the linchpin of his opinion that Par's generic Exforge products infringed the '197 Patent because its ANDA specifications purportedly would have permitted Par to manufacture an infringing product. At his deposition, Mr. Johnson conceded that he searched for but could not find a case decided at or before the time of the NLPA that supported his infringement theory. Ex. 2, Johnson Dep., at 219:25-220:19. Nevertheless, he relied on *Sunovion* because he contends that "the case didn't establish a law." *Id*. at 221:3. But Mr. Johnson cites no prior caselaw. *Id.* at 220:9-19. He cannot rely on a case decided *after* the NLPA was signed to support his opinion about the state of the law *when* the NLPA was signed.

Third, Mr. Johnson relied on facts not in existence at the time of the NPLA. Most notably, his opinions on induced infringement of claim 1 of the '728 Patent are based on facts unavailable to any of the parties when they executed the NPLA. Mr. Johnson admits that Par's originally filed ANDA did not induce infringement and would not have infringed claim 1 until a labeling change ***in September 2012, ten months after the execution of the NPLA on December 2, 2011***. Ex. 1, Johnson Rpt., ¶ 464; Ex. 2, Johnson Dep., at 280:8-19. Nevertheless, he relies upon infringement of claim 1 as an integral part of his patent strength analysis because, in his view, "reasonable companies in both Novartis's and Par's positions would have been paying close attention to any labeling recommendations provided by the FDA for products used in the treatment of hypertension." Ex. 1, Johnson Rpt., ¶ 467. But none of the correspondence produced in this case

reflects that Novartis or Par patent attorneys were even apprised of the upcoming labeling change, much less that they believed that that change was pertinent to the infringement issue or included it in their analysis. Moreover, Mr. Johnson merely assumes that Par was required to "match the corresponding brand labeling." *Id*. ¶ 467. But, if Par had been concerned about the impact of the labeling change on the infringement issue, FDA regulations provide for the "omission [from ANDA labeling] of an . . . aspect of labeling protected by patent." 21 CFR § 314.94(a)(8)(iv). Mr. Johnson does not address how Par's ability to carve the language out of its ANDA label would have impacted his patent strength opinions.

B. Mr. Johnson's Opinions About the Merits of Novartis's Patent Claims Are Contrary to Evidence of Defendants' Beliefs.

Although Defendants have withheld on privileged grounds many documents reflecting their subjective assessment of how likely Novartis was to prevail ***if*** it had asserted the '197 and '728 Patents against Par's generic Exforge, their internal documents are unequivocally inconsistent with Mr. Johnson's opinion that Novartis was likely to prevail. Par submitted certifications to the FDA that "in its ***opinion*** and to the best of its ***knowledge***," the '197 and '728 Patents were "invalid, unenforceable, or will not be infringed" by Par's generic Exforge. Ex. 12, PAR-000065547, at -578-79 (emphasis added). Novartis agreed that Par had "already designed around" the '197 Patent. Ex. 21, NPC_02028740, at -806. It also "agreed" with the assessment of investment broker Morgan Stanley assigning "a high probability that Exforge will face generic competitors in 2012 due to likely invalidation of their pivotal . . . 6,395,728 patent[]." Ex. 25, NPC_01520380, at -380 (evaluating an analysis in Ex. 48, NPC_01881056, at -059). Mr. Johnson's opinions formed in 2021 that Novartis was likely to win should be excluded because they contradict Defendant's own contemporaneous evidence from before the time the NPLA was executed. *Barnett v. Pa Consulting Group, Inc.*, 35 F. Supp. 3d 11, 19 (D.D.C. 2014) (noting "the unremarkable proposition that an

expert witness's testimony should be excluded as unreliable if it is based on assumptions that are contradicted by his or her party's own evidence").

Mr. Johnson's opinion that Novartis was likely to win is also inconsistent with the settlement that Novartis and Par negotiated. Together, the '197 and '728 Patents afforded Novartis 2,481 days of potential exclusivity.[11] But during settlement negotiations, Novartis and Par both anticipated Novartis surrendering 85-90% of that exclusivity period. Par's first draft of the License Agreement proposed a royalty-free license with an entry date of July 1, 2013 (Ex. 45, PAR-000458637, at -639), corresponding to Novartis's surrender of ***88.6%*** (i.e., 2,198 out of 2,481 days)[12] of its potential exclusivity period associated with the '197 and '728 Patents. Internal Novartis documents reflect that Novartis had been expecting a settlement with an entry date of September 2013 (Ex. 44, NPC_00552058 at -058), which would correspond to Novartis surrendering ***85.5%*** of its potential exclusivity period, assuming a mid-September entry date (i.e., 2,122 out of 2,481 days).[13] Even under the executed NPLA, which contains the challenged reverse payment, Novartis surrendered over 70% (i.e., 1,743 out of 2,481 days) of its potential exclusivity period.[14] Mr. Johnson's opinion that "reasonable companies" would have anticipated that Novartis was more likely than not to prevail cannot be reconciled with Defendants' expectation that in a settlement with no reverse payment, Novartis would surrender roughly 85-89% of the exclusivity period associated with those patents, or with its ultimate surrender of over 70%.

[11] Par agreed not to enter before the '578 Patent expired on September 21, 2012, and the '197 and '728 Patents would not both be expired until July 8, 2019. Ex. 49, 2008 Orange Book Excerpt, at 4 (showing expiration dates). The time period between these two dates is 2,481 days. *See, e.g.*, https://www.timeanddate.com/date/duration.html.
[12] *See, e.g.*, https://www.timeanddate.com/date/duration.html.
[13] *See, e.g.*, https://www.timeanddate.com/date/duration.html.
[14] *See, e.g.*, https://www.timeanddate.com/date/duration.html.

Mr. Johnson's opinion that reasonable companies would believe that Novartis would prevail in the patent case is also inconsistent with Novartis's decision not to sue Par. Mr. Johnson opines that "Novartis had nothing to gain by bringing suit early." Ex. 2, Johnson Dep., at 92:22-23; Ex. 1, Johnson Rpt., ¶¶ 598-99. But that cannot be reconciled with his other opinions. He acknowledges that, if Novartis had successfully asserted the '197 and '728 Patents against Par in a Hatch-Waxman lawsuit, Novartis would have been entitled to an order precluding FDA approval of Par's generic Exforge until July 8, 2019, ensuring Novartis continued exclusivity for ***more than six years*** beyond the September 2012 expiration of the unchallenged '578 Patent. *Id.* ¶ 624(a); *see also* 35 U.S.C. § 271(e)(4)(A). Because Novartis's cost of litigating was eclipsed by the value to Novartis in maintaining Exforge market exclusivity through July 2019,[15] any reasonable company confident in its patents would have asserted its patents, rather than anticipating surrendering 85.5% of its potential exclusivity period for no royalty. Moreover, after not suing Par on the '197 and '728 Patents, Novartis opted not to sue *any* of the five other generic drug companies who launched their generic Exforge products ***without licenses*** under the '197 and '728 Patents beginning in 2015. Ex. 56, Novartis Responses to Plaintiffs' Third Set of Interrogatories, No. 14, Schedule 1. Novartis's own decision not to enforce the '197 and '728 Patents against any generic manufacturer of Exforge is contrary to Mr. Johnson's conclusion that Novartis had strong claims under those patents.

The inconsistency between Mr. Johnson's opinions about how reasonable companies would evaluate the patent merits and how Novartis and Par actually evaluated them cannot be dismissed on the grounds that Novartis and Par might not be reasonable companies. As a matter

[15] Mr. Johnson concedes that the cost of litigating the '197 and '728 Patents was $7 to $12 million (Ex. 1, Johnson Rpt., ¶ 20) whereas Plaintiffs' economist calculates that the value to Novartis in maintaining exclusivity was over $700 million (Ex. 55, Elhauge Rpt., ¶ 44, Table 3).

of law, antitrust violators are presumed to act as rational economic actors. *See, e.g., Dolphin Tours, Inc. v. Pacifico Creative Service, Inc.*, 773 F.2d 1506, 1511 (9th Cir. 1985) (holding that plaintiffs' damage model "*must* presume the existence of rational economic behavior in the hypothetical free market") (emphasis added); *Murphy Tugboat Co. v. Crowley*, 658 F.2d 1256, 1262 (9th Cir. 1981) (announcing that in "a hypothetical economic construction . . . economic rationality *must* be assumed for all competitors, absent the strongest evidence of chronic irrationality") (emphasis added), *cert. denied*, 455 U.S. 1018 (1982); *Apotex, Inc. v. Cephalon, Inc.*, 321 F.R.D. 220, 235 (E.D. Pa. 2017) (explaining that antitrust damage models "must presume the existence of rational economic behavior in the hypothetical free market"). Absent the assumption of economic rationality, "it will be impossible to keep speculation in check." *Murphy*, 658 F.2d at 1262.

Moreover, Mr. Johnson admitted that he believes that both Novartis and Par are reasonable companies. Ex. 2, Johnson Dep., at 119:5-22 ("[M]y impression is that Novartis is a reasonable company based on years of having been involved in the pharmaceutical industry and knowing over the years how Novartis has behaved and presented itself in the -- as a competitor to clients I represented" and "I have no reason to think that they're unreasonable as a company overall. . . ."; *id*. at 120:8-16 (regarding Par: "[o]nce again, I have the same impression from my years working in the pharmaceutical industry, that they are a respected competitor and that I have no reason to think they behaved unreasonably"). Indeed, there is no evidence that Novartis and Par were unreasonable. They are both sophisticated companies, well-versed in patent litigation, and were advised by both in-house and outside counsel. Ex. 70, NPC_02036477, at -489 (reflecting that Novartis obtained an "external Opinion" from the "Fitzpatricks" law firm); Ex. 46, NPC_02035971, at -980; Ex. 47, NPC_02036011, at -388-391; Ex. 58, Brown Dep., at 25:12-26:12 (Par lawyer describing himself as "patent counsel" responsible for "provid[ing] legal

advice" including "working with internal research and development to design around" relevant patents); Ex. 59, Ferraro Dep., at 13:11-25 (Novartis employee serving as "senior patent attorney" and then vice president of "IP strategy"); Ex. 60, Waibel Dep., at 13:12-22 (Novartis employee serving as "senior patent attorney" and then "head of patent litigation").

VI. CONCLUSION

For the foregoing reasons, the Court should preclude Mr. Johnson from offering his opinion as to how "reasonable companies" would have viewed the strength of the '197 and '728 Patents because those opinions: (1) are based on law and facts that did not exist at the time the NPLA was executed and (2) conflict with Defendants' actual views.

Dated: January 11, 2022

Respectfully submitted:

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that on [INSERT] the foregoing document was served on all counsel via the Court's ECF system.

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